A CLINICAL INVESTIGATION OF CONSERVATIVE TOTAL HIP REPLACEMENT

Senior Honors Thesis (ID 499)

by

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At the beginning of my summer of research with Dr. Brueckmann at Orthopaedics Indianapolis, Inc., I didn't have any idea what arthroplasty meant or that it was performed so frequently. As a result, my first weeks were filled with more questions than answers, and I spent a lot of time in the library reading and gathering information about a topic I was supposed to be an "expert" on by July 31, 1989. To this end, I am grateful to the many people at Orthopaedics Indianapolis, Inc. who patiently answered my questions and helped to orient me to the office: Patty and Marlene who gave me many pointers on successful computer usage, Chloe, Freda, and Karen who helped me find the many patient files I needed, and Susan who graciously let me share her office space. Also, I would like to give a BIG thank-you to Sue Wolfe whose optimistic and carefree attitude was a refreshing welcome everyday in the office. Her willingness to give her opinion and direct me to the right people to answer my questions proved invaluable. Finally, my deepest appreciation goes to Dr. F. Robert Brueckmann whose enthusiasm and genuine interest in all fields of medicine made work not seem like work at all.

In September, 1940, Dr. Austin Moore inserted the first Vitallium metal prosthesis into a human hip.[20,24] In the nearly fifty years since that landmark date, arthroplasty, or the replacement of bones and joints with prostheses, has developed considerably.

Conventional total hip replacement, where the entire head of the femur and the greater trochanter are removed and the center of the femur shaft reamed, has been used successfully in elderly patients with advanced hip disease. This success is due largely to the sedentary activity level of these patients and the age of these patients, since they often die before the prothesis loosens.[6] However, younger, more active patients will most likely outlive the fixation of the components and will require further revisions.[6] For this reason, a more conservative total hip replacement procedure is recommended for younger patients.[5,13] A conservative procedure differs from conventional hip replacement in that only minimal portions of the femoral head and acetabulum are removed when implanting the prostheses. Preserving healthy bone stock not only provides stability to the implant, but also provides a surgical "buffer zone" for revisions of potential failures.[3,13,14] This allows for further surgical adaptations such as arthrodesis, the fusing and pinning of a joint, and conventional total hip replacement to be performed later if necessary.

The goal of conservative total hip arthroplasty is to minimize the removal of healthy bone in the region of the hip so that alternative treatments can be performed in the event of failure.[5] Total Articular Replacement Arthroplasty, or the TARA procedure, invented by Dr. Charles O. Townley, is one type of conservative treatment which accomplishes this goal. The TARA procedure, in conjunction with the TARA implants, involves both arthroplasty and hemiarthroplasty, in which only the femoral component is implanted, and has been used since 1952. The major objectives of the TARA design are to preserve healthy bone stock, maintain the normal anatomy and mechanics of the hip joint, and to approximate the normal transmission of stress to the supporting femoral bone.[27] (FIGURE 1)

To reach these objectives, it must be determined that the patient has the necessary anatomical and physiological characteristics needed to maintain conditions for successful total hip arthroplasty. Several criteria, both preoperative and intraoperative, exist to achieve this end. (FIGURE 2) The surgeons involved in this study generally followed these criteria. First, the patient must have good bone quality as assessed from x-rays of the hip.[7] This allows for minimal bone removal during surgery and provides a solid base to attach the prosthesis. Also, after remodeling the femoral head, the bone tissue should be alive and healthy to ensure that further degeneration does not readily occur. A physiological age of less than sixty years old is a second criteria.[7] Older patients with higher activity levels also fulfill this criteria. The TARA procedure is highly recommended for younger (less than sixty years old) patients due to the conservative technique used and its allowance for further revisions upon eventual failure. However, the decision to do a total hip arthroplasty on a young patient must be made with the knowledge that the risk of eventual failure is much higher than it is for an

FIGURE 1

Objectives

The TARA Design

- Preserve healthy bone stock
- Maintain normal hip anatomy
- Maintain normal hip mechanics
- Normal transmission of stress to femoral bone

C.O. Townley

FIGURE 2

Operative Criteria

- Good bone quality
- Physiological age less than 60 years
- Minimal acetabular reaming needed

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individual who is older than forty-five years old.[8] A third criteria is the preservation of the subchondral plate during acetabular reaming.[7] This layer of very dense bone, located just beneath the articulating surface of the acetabulum, endures the primary joint forces during weight bearing activities. By keeping the femoral component diameter to a minimum, only a minimal amount of acetabular bone stock needs to be removed, thus preserving the subchondral plate. By fulfilling these objectives and criteria, this procedure has the potential to be more effective than previous articular cup surfacing and fill the need for a dependable and conservative total hip replacement.

The TARA procedure eliminates many of the mechanical and physiological factors that have led in the past to prosthesis failure. (FIGURE 3) First, it removes the vascularly damaged portion of the femoral head.[27] This reduces the potential for further collapse of the damaged bone since the diseased portion is excised prior to seating the implant in place. Second, the mechanical design of the TARA components provide for precise positioning during surgery on the femoral head and in the acetabulum.[27] The thin stem extending from the center of the cup curves to follow the pattern of the medullary canal in the femur. During weight bearing, the stem is forced to the lateral wall of the femoral canal, so positioning along the medial wall is essential to ensure that enough bone is present for stability. The stem also provides a protective splinting effect on the femoral neck, helping to reduce the risk of femoral neck fractures.[8,14] Third, the flat-planed anchoring surface reduces sheer forces and

FIGURE 3

TARA Surgical Procedure

- Removes vascularly damaged bone
- Precise positioning
- Maximum mechanical stability
- Minimal femoral reaming

C.O. Townley

provides maximum mechanical stability.[27] The femoral head is remodeled to be cylindrical in shape, providing a fitted seat for the femoral prosthesis so that only the head, not the stem, bears the substantial joint stresses. Fourth, the design of the TARA femoral prosthesis does not require reaming of the femoral neck cortex, so this critical supportive bone is not lost.[27] Seating the TARA prostheses requires only minimal bone removal on both the femoral and acetabular sides, and is consequently considered a conservative total hip replacement.[6]

The purpose of the present study was to review a group of patients who had undergone Total Articular Replacement Arthroplasty using the TARA procedure. The information gathered was used to determine how long after the initial operation the components could be expected to remain intact, to make a correlation between the age of the patient and the success of the prostheses, and to determine which component was most likely to fail.

MATERIALS AND METHODS

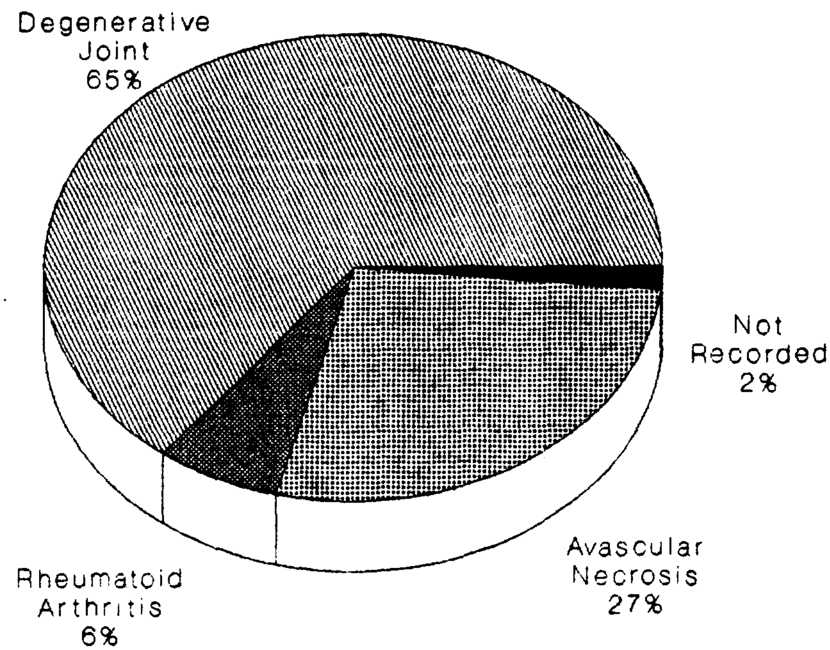
From December 1979 through May 1989, eighty-two total articular replacement arthroplasties using the TARA procedure were performed in 62 patients. Seventy-four percent of these patients were seen in an office visit or were followed by a telephone interview after January 1, 1989. The 9.7% of the patients who had a failure determined by removal of the TARA components were not contacted since their surgery no longer involved the TARA procedure. The remaining 16.1% of the patients were unable to be contacted due to the lack of a forwarding address or telephone number. The average length of follow-up was 28.6 months. In the statistical analysis, it was assumed that these patients had successful surgeries up until the current date and that they would have contacted their surgeon had the pain of failure been present. Only three of the people contacted by telephone reported symptoms characteristic of failure, supporting this assumption.

The patient group was initially identified through an office computer system using the current procedural terminology (CPT) coding system. Those patients whose surgical codes corresponded to arthroplasty, revision or removal of a prosthesis, cup arthroplasty, hemiarthroplasty, or any other total hip replacement which involved the TARA procedure, were included in this study. There were twenty-seven females and thirty-five males. The average age at the time of surgery was 49 years, ranging from thirteen to eighty years. Twenty-eight patients had involvement of the right hip; twenty-seven, of the left hip; and seven patients had bilateral involvement. The initial operations were performed by eight orthopaedic surgeons at Orthopaedics Indianapolis, Inc. in Indiana, and one orthopaedic surgeon in Michigan.

The diagnoses of the patients can be grouped into three distinct categories; degenerative joint disease, avascular necrosis, and rheumatoid arthritis. (FIGURE 4) Forty (64.5%) of the patients had a diagnosis of degenerative joint disease, including degenerative arthritis and osteoarthritis. These conditions are characterized by degeneration of the joint cartilage and osteophyte production, which is the calcification of tendon tissue. They are most likely caused by advancing age and long continued use, especially in weight bearing joints. This helps to

FIGURE 4

INITIAL DIAGNOSIS
Diagnosed 1979-1989



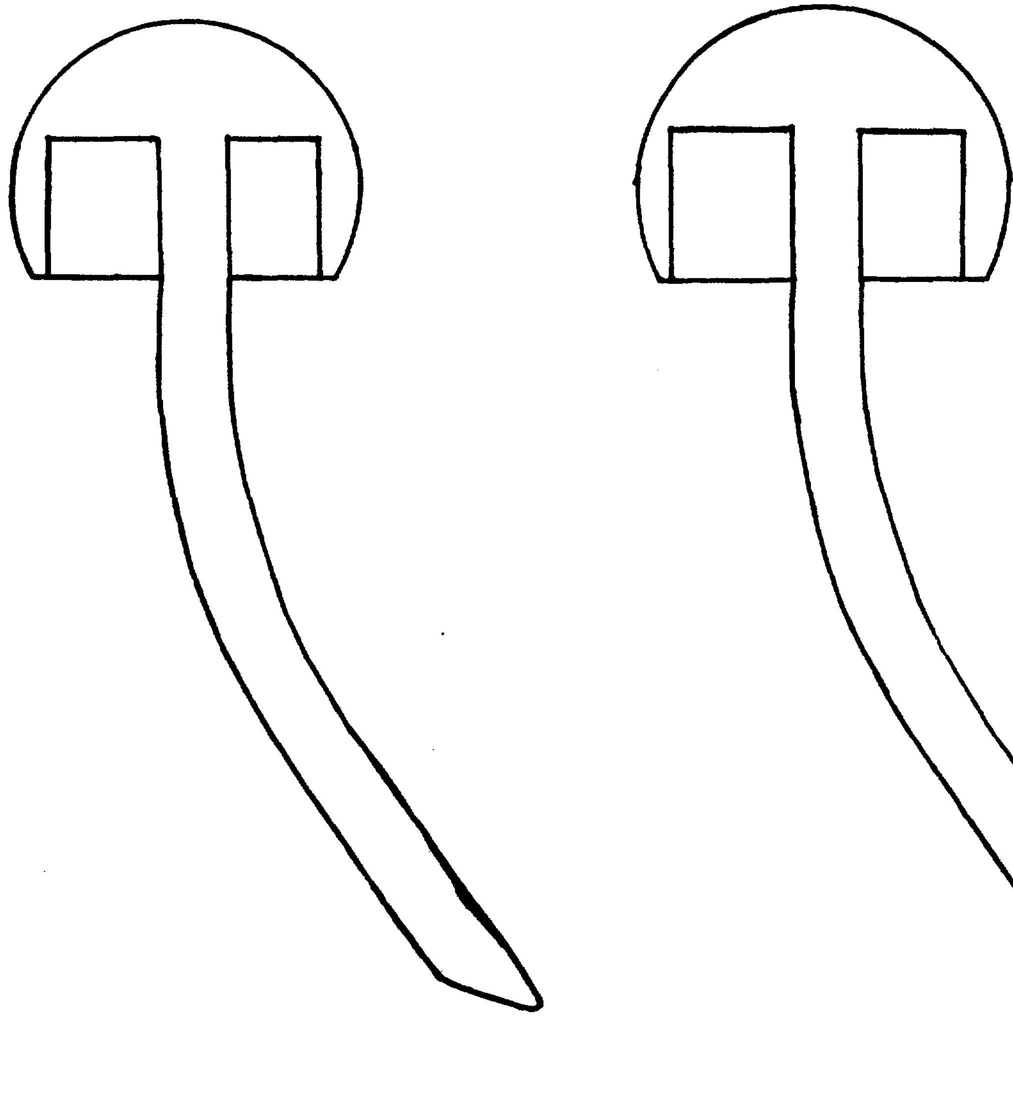
International Classification of Diseases

explain its relative frequency in obese people and in those with mechanical skeletal defects.[1] Degenerative joint disease is rarely disabling unless the hip joint is involved.[1,19] Seventeen (27.4%) of the patients were diagnosed with avascular necrosis, including osteonecrosis. These conditions result when the blood supply to the head of the femur is limited causing bone cell death. This may be caused by trauma to the joint area, high corticosteroid use, alcoholism, renal transplant complications, lupus erythematosus, and a variety of other factors.[10] Four (6.5%) of the patients had a diagnosis of rheumatoid arthritis. This is a chronic, progressive disease, causing pain, stiffness, muscle atrophy, and eventual deformity. Though the cause of rheumatoid arthritis is unknown, it has been linked to heredity, infection, and the metabolic process, among other possibilities.[1]
One (1.6%) patient's diagnosis was not recorded.

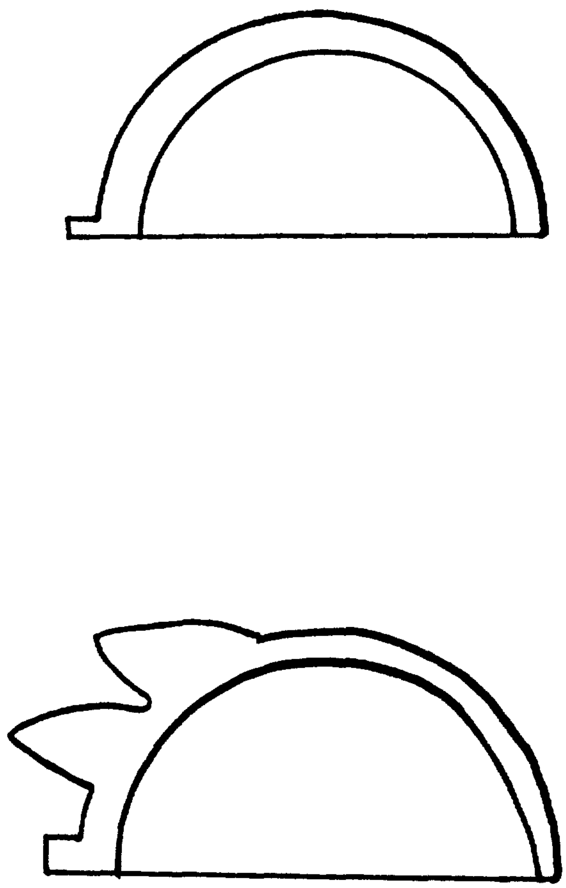
The implants used in the TARA procedure consist of a spherical chrome cobalt metallic fixed femoral cup and a polyethylene acetabular component.[27] (FIGURE 5 & 6) They are available in eight matched sizes with the femoral head diameters ranging from 38 to 54 millimeters. The inner anchoring surface of the femoral implant is a flat-topped cylinder which caps the remodeled femoral head. The acetabular implants are hemispherical cups whose inner diameters match the femoral heads. Some acetabular cups are modeled as a cock's comb cup. This design features a dual prong comb which is implanted into the pelvic bone to prevent the implant from rotating and becoming displaced.

To fix the implants to the bone, an acrylic bone cement is

Townley TARA Femoral Components



Townley TARA Acetabular Components



used, or porous-coated components are used to allow for biological fixation. Acrylic bone cement, such as polymethyl methacrylate, was developed in the early 1960s by Sir John Charnley.[15] When used to cement prostheses into elderly patients, it has proven very successful. However, the cement is unable to sustain the higher stress loads endured by younger, more active adults. For this reason, biological fixation, or bone ingrowth fixation, is becoming more common. With this type of fixation, the surfaces of the implant which contact the bone are covered with a porous-coating. Porous-coating consists of chrome cobalt metal beads or wire mesh bonded to the implant surface which increases the surface area and provides pores for the bone to integrate into the metal. Since the TARA procedure is most often used in younger adults, porous-coated implants are appropriate to use. In theory, porous-coating should allow the bone to grow into the spaces of the metal and become fixed without the need to use any cement.[11,15] However, complications exist, from the metal being a suspected carcinogen, to the prosthesis not being fixed firmly due to the continued degeneration of the bone.[4,11] These complications have caused the FDA to recommend that cement be used with the implants regardless if they are porous-coated or not. Information concerning the use of cement or the acetabular cockscomb cup was not consistently recorded in the operative notes and thus was not included in this study.

INCIDENCE OF FAILURE

The overall incidence of failure was judged by walking ability, range of motion, and pain. Specific questions about the significance of pain included: the ability to walk without a cane or crutches, the amount of pain medication being taken, the amount of range of motion available to perform daily activities, stair climbing ability, and pain or stiffness caused by sitting, standing, or walking. In order to determine failure, the following criteria were used. (FIGURE 7)

1. Removed prosthesis due to mechanical failure, infection, or pain.
2. Revised arthroplasty due to mechanical failure, infection, or pain.
3. Significant pain interfering with the normal demands of daily living.

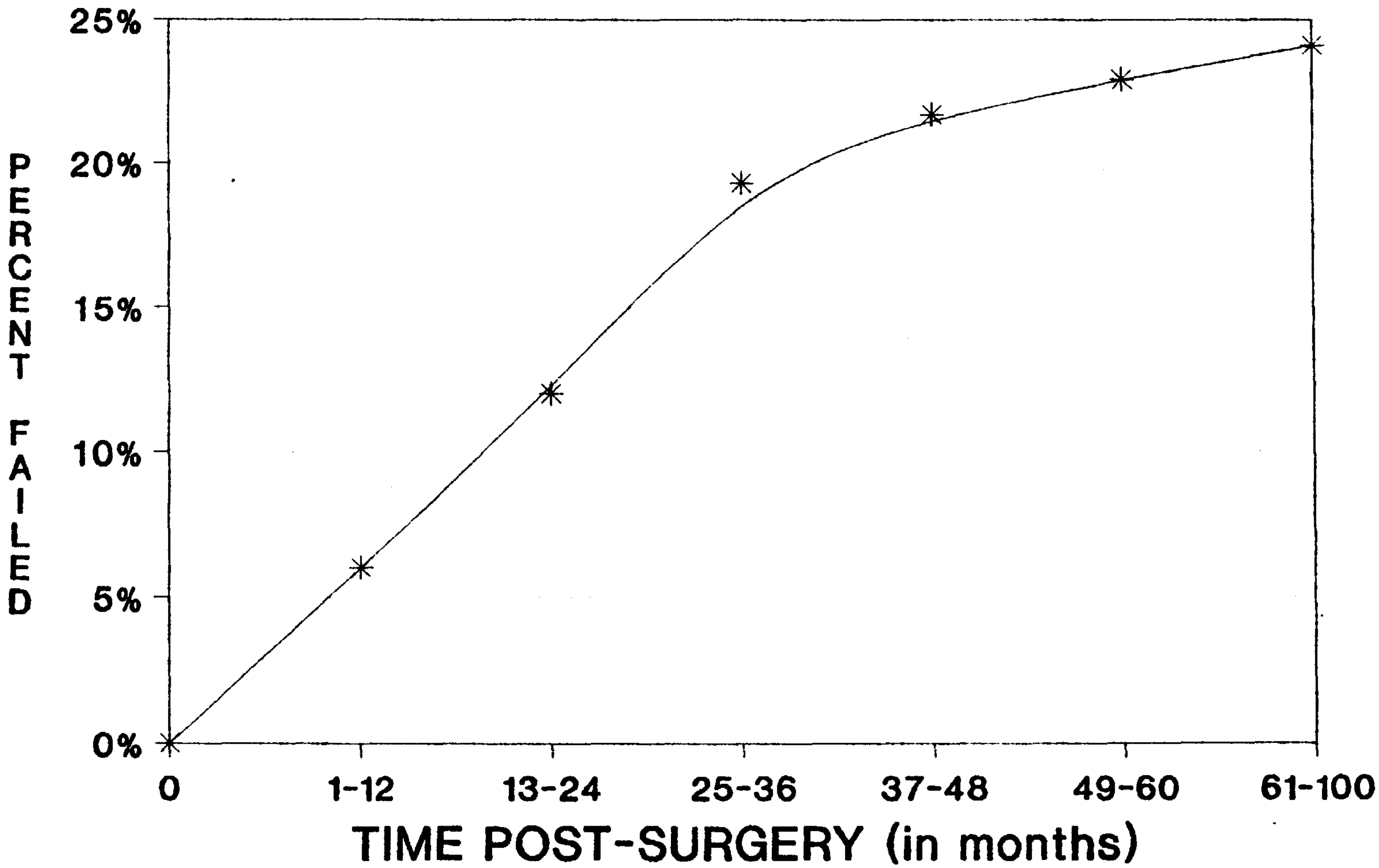
Altogether, there were twenty procedure failures in eighteen patients, including pain defined failures and those requiring revision or prosthesis removal. This gives an overall failure rate of 24.4%, implying that one in every four hip replacements involving the TARA procedure failed when performed by one of the doctors involved in this study. (FIGURE 8) A vast majority of the failures occurred during the first three years following surgery. After that period, the failure rate only increased 5%, which greatly increases the patients' odds for a successful hip replacement if they can survive those first precarious years. Ten of the failures involved the acetabular component; eight, involved the femoral component; and two, involved both components. (FIGURE 9) The average age of these patients was fifty years old, providing evidence that the younger, more active patients put more

FIGURE 7

Failure Criteria

- Removed prosthesis
- Components revised
- Significant pain

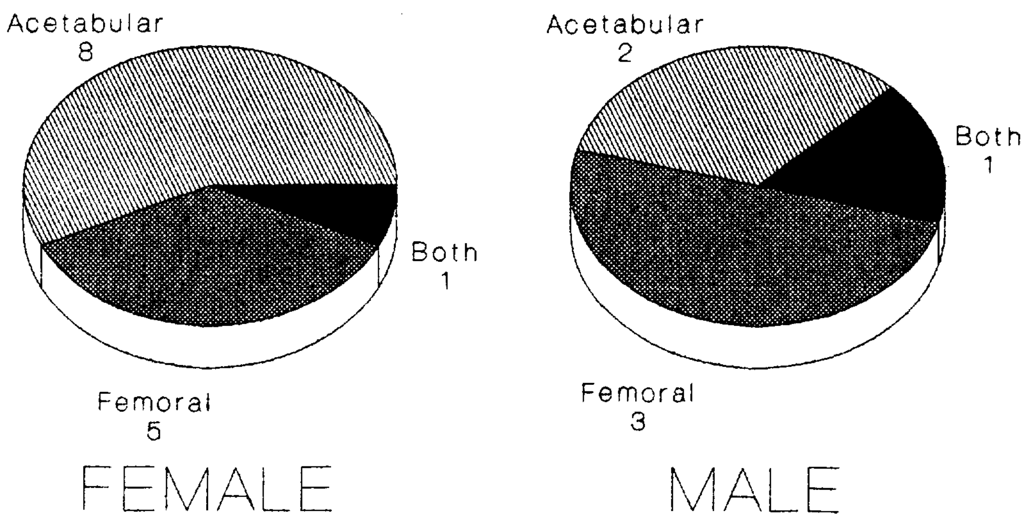
INCIDENCE OF FAILURE



Surgery performed 1979-1989

FIGURE 8

FAILED IMPLANTS
(Removed or Replaced)



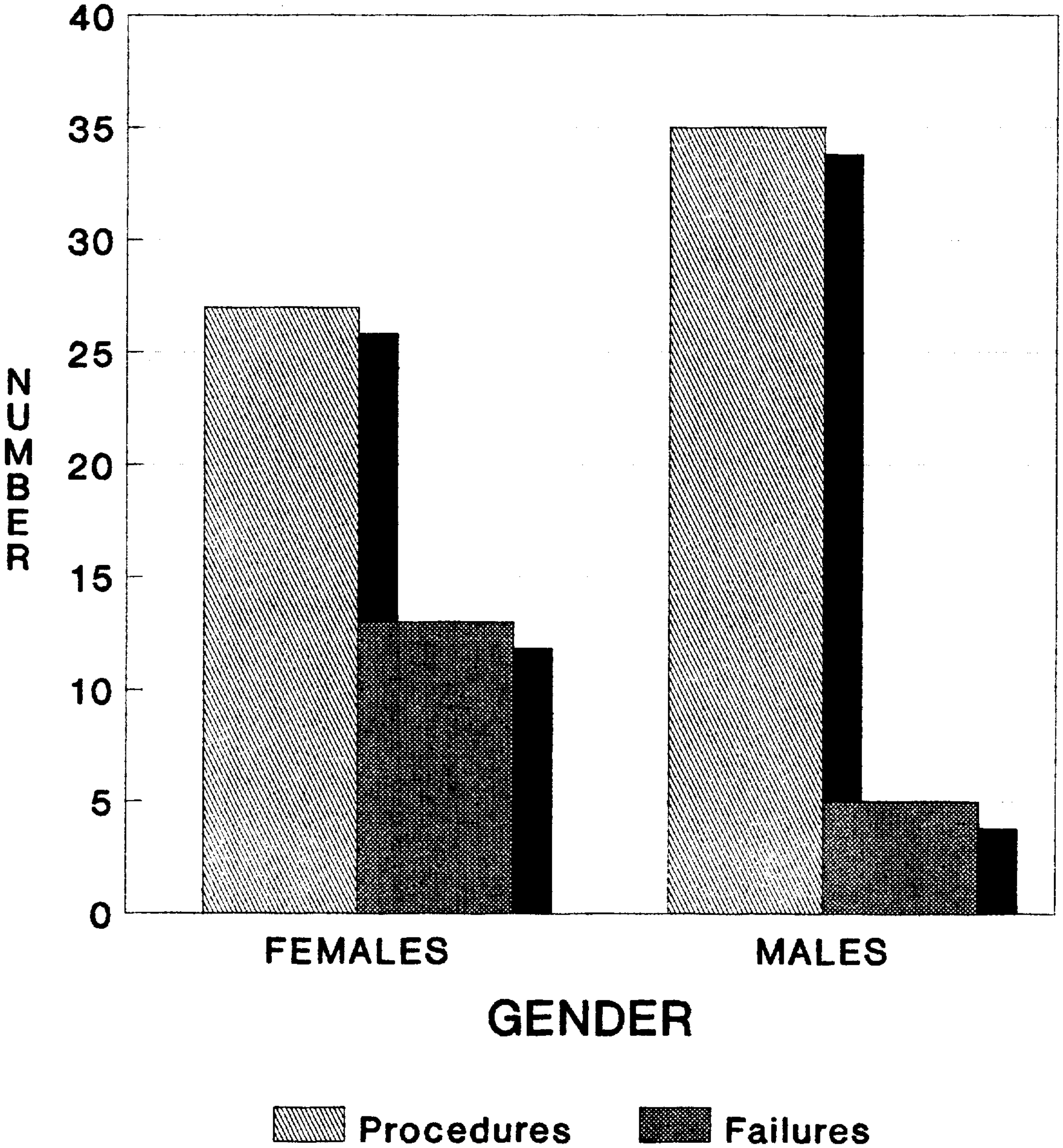
Surgery performed 1979-1989

patients put more stress on the implants, inducing an increased chance of failure. The average length of time before these patients experienced prosthesis failure was 27.6 months, ranging from two months to one hundred months.

It is interesting to note that more than twice as many women experienced failure as men, even though more men underwent surgery. (FIGURE 10) This may be due to the general bone quality found in women which tends to be softer and less able to stabilize the prostheses, the smaller size of the bones in females, and the degenerative characteristics of female bones as they age past menopause. This result is contradictory to previously reported studies.[9,22] Also, those patients between the ages of forty and sixty years old were twice as prone to failure as those patients over sixty years of age, and those younger than forty years of age. (FIGURE 11) This may be due to the lower activity level of the older patients, a less amount of time allowed for follow-up so that the procedure had not had an opportunity to fail, or the stronger and more dense bone stock found in the younger patients.

According to Wolff's Law, which states that a structure adapts to it's function,[23] any modifications made during joint replacement cause the bone to remodel and adapt to the new stresses. If the initial implantation technique is poorly aligned or unstable, this adaptation may lead to rapid instability and failure. Thus, the life of fixation may be determined by the strength of the initial fixation, the degree of stress at the bone and implant interface, and the rate of bone repair.[9] The issue of the success of cement versus biological fixation using porous-coating is still being

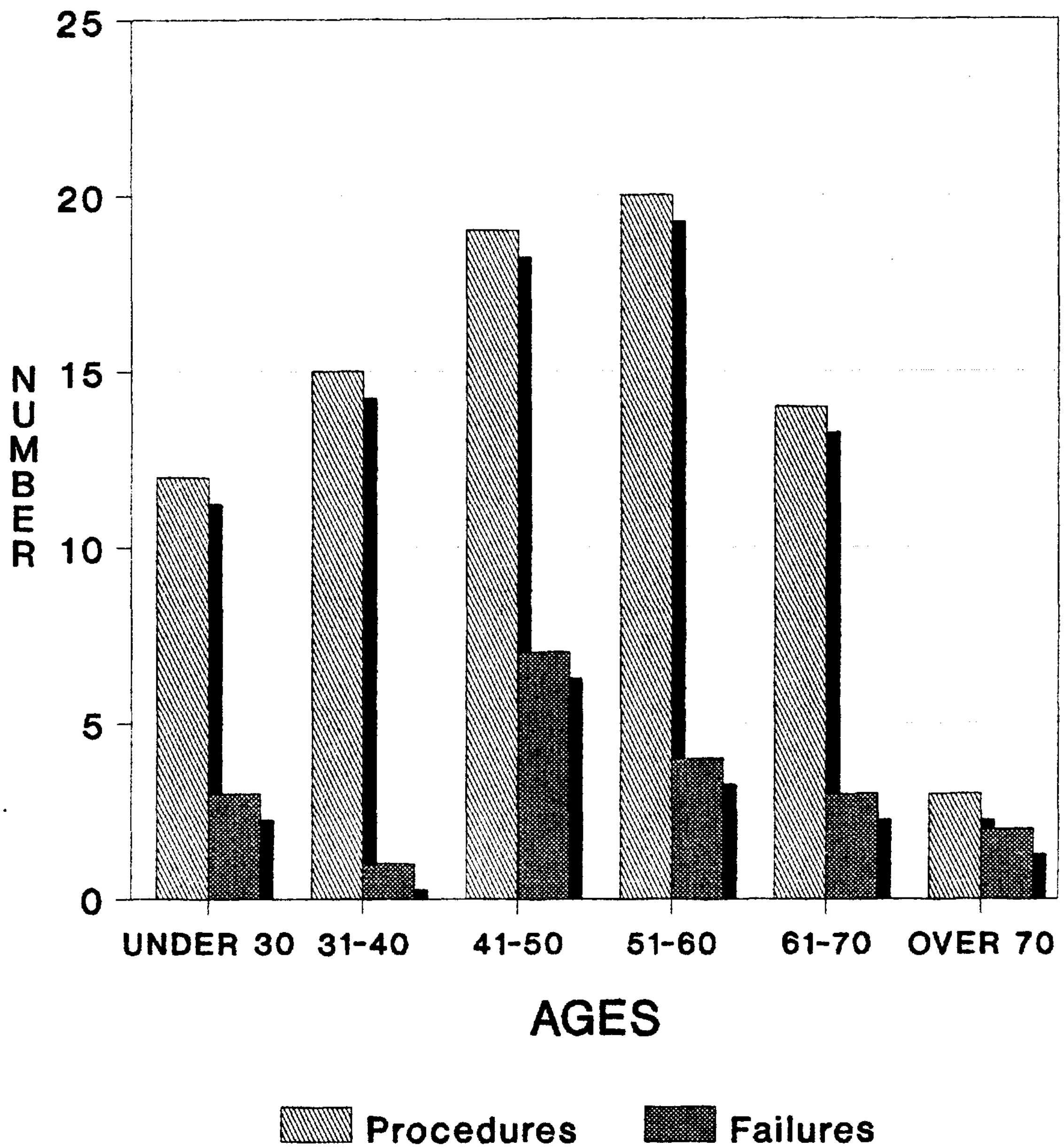
PROCEDURES AND FAILURES
(Gender Comparison)



Surgery performed 1979-1989

FIGURE 11

PROCEDURES AND FAILURES
(Age Comparison)



Surgery performed 1979-1989

debated in regards to the method of fixation. Breakdown of either fixation may be due to mechanical factors and applied stress. These involve joint forces produced by the hip musculature, the patient's activity level, and the patient's body weight. Biologically, the rate of repair is influenced by the advancing degenerative disease characteristics of the bone, infection, and hormonal and steroidal factors.

DISCUSSION

The incidence of failure in this study is unacceptably high, though it is an improvement over previously reported results involving total hip replacement. In other studies, including both conventional and conservative hip arthroplasty, the reported failure rates have varied widely. Generally, those studies involving the TARA procedure have produced the most promising results. In analyzing component failure in 67 hips with TARA implants, Head reported an expected failure rate of 34.3% after a follow-up period averaging 3.3 years. However, Townley reported a failure rate of only 6% in 222 hips involving the TARA procedure that were followed for four years. As inventor of the TARA procedure and the TARA prostheses, Townley's expertise is expected to produce such outstanding results. Cohn et al., reported a 7% failure rate in 33 TARA procedures followed for 3.5 to 7 years. This low rate is explained by the strict selection criteria Cohn followed when deciding which patients should undergo the TARA procedure. These criteria are the same as those previously mentioned in this report.

With conventional total hip replacement, the rates of failure reported are higher. Chandler et al., in a study involving 33 hips in patients younger than 30 years old, reported impending failure or total failure in 57% of the hips after a five year follow-up. Dorr et al., reported unsatisfactory results in 28% of patients who were less than 45 years old and were followed for over five years.

In this study, the number of components which failed are almost equally divided between the femoral and acetabular sides. Other results reported in literature show more acetabular complications.[13,27] It is the opinion of Townley that the use of the TARA fixed femoral cup for hemiarthroplasty is the best currently available procedure for young, active patients with a sound, concentric acetabulum.[27] As stated previously, the TARA femoral cup allows for later revision surgery if needed, it removes the vascularly damaged bone, the minimal femoral reaming leaves the healthy bone to provide support, and it's flat-topped cylinder shape with the thin stem design provides maximum mechanical stability and precise positioning. These benefits are invaluable, especially when the implant is used in a young patient.

To help reduce the rate of failure, loosening of the components needs to be controlled and prevented. Mechanical forces can be reduced to reach this end. This involves proper positioning of the components to reduce sheer stresses and promote stability. Also, the surgeon could encourage the patients to keep their body weight low, and to avoid stressful activities such as running and heavy weight lifting. Other factors that may lower the failure rate include proper cementing technique, and removing only the diseased bone, leaving the healthy bone for support. As the biomechanical design of the prostheses improve and the cement versus porous-coat fixation debate is resolved, lower rates of failure should result. Excellent results can be obtained if proper surgical technique is adhered to and strict selection criteria is followed.[7]

The TARA procedure has shown to be an excellent choice for total hip replacement in younger patients. It's conservative nature not only allows for further revisions, but it uses the patients' youthful structural characteristics such as strong bone stock and minimal vascular damage to a definite advantage. It's immediate results in decreasing the pain and increasing the range of motion make the TARA procedure very satisfactory to the patients, an impression reflected often in the conversations shared by those involved in this study.

APPENDIX A

(Patient Data)

PATIENT LIST

CASE NUMBER	PATIENT NAME	PATIENT NUMBER
1.	Julia Harper (1)	103985
2.	Julia Harper (2)	103985
3.	Horace King	156531
4.	Amos Dawson (R)	234508
5.	Amos Dawson (L)	234508
6.	William Harden (1)	244929
7.	William Harden (2)	244929
8.	Ernestine King	370126
9.	Linda Youmans (hemi)	383732
10.	Linda Youmans (total)	383732
11.	Linda Youmans (revision)	383732
12.	Shanelle Erby	461660
13.	Helen Williams	466468
14.	Florence Bymaster	489077
15.	Ruth Mount (1)	508632
16.	Ruth Mount (2)	508632
17.	Gregory Dowden (hemi)	555479
18.	Gregory Dowden (total)	555479
19.	Carmen Gray	564605
20.	Harold Hendricks (1)	571016
21.	Margaret Coy	594040
22.	Gwendolyn Carter	628115
23.	Heidi Byers	674176
24.	Raymond Herring	704482
25.	Michael Dugan	758353
26.	Gene Horner (1)	787663
27.	Gene Horner (2)	787663
28.	Philip Carter	797022
29.	Joseph Taylor (L)	803677
30.	Joseph Taylor (R)	803677
31.	James Bogard	817074
32.	Richard Buntin	840394
33.	James Edwards	854972
34.	Patricia Budreau (L)	862142
35.	Patricia Budreau (R)	862142
36.	David Fisher	874795
37.	Norman Hughey	875872
38.	Delores Hastings (R)	880574
39.	Delores Hastings (L)	880574
40.	Martha Boleman	886793
41.	Guna Asons	887978
42.	Max Brown	888060
43.	Robert Bell	920460
44.	Patricia Yeager (1)	933465
45.	Patricia Yeager (2)	933465
46.	Ralph Muckerheide (R)	943959
47.	Ralph Muckerheide (L)	943959
48.	Ree Jean Frazee	952710

PATIENT LIST

CASE NUMBER	PATIENT NAME	PATIENT NUMBER
49.	Kathryn Gowin	956694
50.	Florence Weinman	985759
51.	Louise Bowling (1)	998990
52.	Louise Bowling (2)	998990
53.	Louise Bowling (3)	998990
54.	Ernestine White	999245
55.	Kelly Million (R)	1000535
56.	Kelly Million (L)	1000535
57.	Kenton Clark	1001590
58.	Terry Gruenholz	1003356
59.	Kenneth Alles	1016156
60.	Alan Retherford	1018337
61.	Janie Smith (R)	1034278
62.	Janie Smith (L hemi)	1034278
63.	Thomas Sleet (1)	1070037
64.	Thomas Sleet (2)	1070037
65.	Janett Hoke (1)	1075934
66.	Janett Hoke (2)	1075934
67.	Berneice Anderson (1)	1087089
68.	Berneice Anderson (2)	1087089
69.	George Alexander	1087532
70.	Max Frazee	1089596
71.	Jack Woody	1089617
72.	Yvette Edmonds	1090843
73.	April Johnson	1092066
74.	Mary Veracco	1092513
75.	Eddie Guffey	1093554
76.	William Pierce	1095725
77.	Lyman Halverson	1101472
78.	Benny Lackey	1101839
79.	Robert Murray	1105559
80.	Jerry Todd	1105677
81.	Kenneth Chavis	1106251
82.	Patrick Murray	1106340

PATIENT STATISTICS

CASE#	SEX	AGE[1]	HIP	SURGERY DATE	FAIL DATE[2]	FAILED COMP[3]	DIAGNOSIS[4]
1 \	F	28	R	12/28/79	4/28/84	acet.	DJD
2*/	F	32	R	4/28/84	---	---	
3	M	59	L	11/13/85	---	---	DJD
4 \	M	64	R	3/16/84	---	---	DJD
5 /	M	68	L	2/23/88	---	---	
6 \	M	57	L	10/9/79	6/14/82	femr.	AVN
7*/	M	60	L	6/14/82	---	---	
8	F	66	R	12/10/86	---	---	DJD
9 \	F	40	L #	8/19/80	---	---	DJD
10 |	F	41	L	1/16/81	---	---	
11*/	F	41	L	1/16/81	8/ /82	acet.	
12	F	20	L	10/21/86	1/27/89	acet.	DJD
13	F	47	R #	3/4/81	6/20/89	femr.	AVN
14	F	80	L	4/1/81	---	---	DJD
15 \	F	62	L	12/12/80	7/13/82	acet.	DJD
16*/	F	64	L	7/13/82	DIED	1984	
17 \	M	31	R #	12/15/82	---	---	DJD
18*/	M	32	R	8/29/84	---	---	
19	M	49	R	1/5/88	---	---	DJD
20	M	41	R	11/13/85	11/14/88	both	DJD
21	F	61	R	10/19/84	---	---	DJD
22	F	38	L	1/11/85	---	---	DJD
23	F	17	L	9/22/88	---	---	AVN
24	M	55	L	7/13/84	---	---	DJD
25	M	44	R	3/7/89	---	---	AVN
26 \	M	58	R	3/10/87	1/27/88	acet.	DJD
27*/	M	59	R	1/27/88	---	---	
28	M	49	R	9/10/84	---	---	DJD
29 \	M	49	L	2/17/84	---	---	DJD
30 /	M	53	R	2/2/88	---	---	
31	M	58	R	11/29/84	---	---	DJD
32	M	48	L	8/27/84	10/24/85	femr.	DJD
33	M	49	L #	8/10/84	---	---	DJD
34 \	F	36	L	7/20/84	---	---	RHAR
35 /	F	38	R	1/8/86	---	---	
36	M	63	R	8/10/87	---	---	DJD
37	M	55	R	12/27/85	---	---	DJD
38 \	F	25	R	9/13/84	---	---	AVN
39 /	F	26	L	9/6/85	---	---	
40	F	61	L #	5/22/85	---	---	AVN
41	F	50	L	11/15/84	---	---	DJD
42	M	51	L #	10/26/84	---	---	AVN
43	M	59	R #	5/19/85	9/17/86	femr.	AVN
44 \	F	56	L	12/4/85	3/30/88	acet.	DJD
45*/	F	59	L	3/30/88	---	---	
46 \	M	46	R	11/13/85	---	---	DJD
47 /	M	46	L	11/27/85	---	---	
48	F	55	R #	7/26/85	---	---	DJD
49	F	63	R	10/18/85	1/ /89	both	RHAR

CASE #	SEX	AGE	HIP	SURGERY DATE	FAIL DATE	FAILED COMP	DIAGNOSIS
50	F	52	L	1/29/86	---	--	DJD
51 \	F	46	R	2/5/86	3/26/86	acet.	DJD
52*]	F	46	R	3/26/86	11/14/86	acet.	
53*/	F	46	R	11/14/86	---	---	
54	F	57	R	4/2/86	---	---	DJD
55 \	F	26	R #	3/30/88	---	---	AVN
56 /	F	27	L	4/5/89	---	---	
57	M	51	R	9/23/86	---	---	DJD
58	M	36	L #	12/23/86	---	---	AVN
59	M	31	L #	5/28/86	---	---	AVN
60	M	50	R	5/15/86	---	---	DJD
61 \	F	38	R #	7/21/86	---	---	AVN
62 /	F	38	L #	10/20/86	5/4/89	femr.	
63 \	M	65	R	11/25/86	5/30/89	acet.	DJD
64*/	M	67	R	5/30/89	---	---	
65 \	F	49	L	12/16/86	10/13/87	acet.	DJD
66*/	F	50	L	10/13/87	---	---	
67 \	F	74	R	1982	1983	femr.	RHAR
68*/	F	75	R	1983	4/7/87	femr.	
69	M	70	L	3/22/88	---	---	DJD
70	M	70	R	7/17/87	---	---	DJD
71	M	53	R	1980	---	---	UNK
72	F	27	L #	9/29/87	6/19/89	femr.	AVN
73	F	16	R #	10/20/87	---	---	AVN
74	F	55	R	1/3/89	---	---	DJD
75	M	19	L	2/16/89	---	---	AVN
76	M	65	L	4/26/88	---	---	DJD
77	M	34	L #	9/6/88	---	---	AVN
78	M	13	L #	9/28/88	---	---	DJD
79	M	34	R #	2/28/89	---	---	DJD
80	M	53	L	5/24/89	---	---	DJD
81	M	17	L	5/31/89	---	---	AVN
82	M	36	R	3/28/89	---	---	RHAR

* indicates revision of a TARA procedure surgery
\ indicates patients who have undergone multiple TARA surgeries
/
\# indicates hemiarthroplasty (femoral prosthesis) surgery only

1. Age at time of surgery

2. Date revision surgery was needed as a result of significant pain or prosthesis loosening.

3. Prosthesis, acetabular, femoral, or both, which was causing the pain of failure or was revised due to loosening.

4. Diagnosis of hip disease at time of surgery.

AVN	-	Avascular Necrosis
	-	Osteonecrosis
DJD	-	Degenerative Arthritis
	-	Degenerative Joint Disease
	-	Osteoarthritis
RHAR	-	Rheumatoid Arthritis
UNK	-	Unknown

PATIENT STATISTICS

CASE#	SEX	AGE[1]	HIP	SURGERY DATE	FAIL DATE[2]	FAIL TIME[3]	SUCCESS TIME[4]
1 \	F	28	R	12/28/79	4/28/84	52	--
2*/	F	32	R	4/28/84	---	--	62
3	M	59	L	11/13/85	---	--	20
4 \	M	64	R	3/16/84	---	--	61
5 /	M	68	L	2/23/88	---	--	14
6 \	M	57	L	10/9/79	6/14/82	32	--
7*/	M	60	L	6/14/82	---	--	50
8	F	66	R	12/10/86	---	--	29
9 \	F	40	L	8/19/80	---	--	24
10	F	41	L	1/16/81	---	--	19
11*/	F	41	L	1/16/81	8/ /82	19	--
12	F	20	L	10/21/86	1/27/89	27	--
13	F	47	R	3/4/81	6/20/89	100	--
14	F	80	L	4/1/81	---	--	99
15 \	F	62	L	12/12/80	7/13/82	19	--
16*/	F	64	L	7/13/82	DIED 1984		24
17 \	M	31	R	12/15/82	---	--	76
18*/	M	32	R	8/29/84	---	--	56
19	M	49	R	1/5/88	---	--	18
20	M	41	R	11/13/85	11/14/88	36	--
21	F	61	R	10/19/84	---	--	56
22	F	38	L	1/11/85	---	--	10
23	F	17	L	9/22/88	---	--	7
24	M	55	L	7/13/84	---	--	60
25	M	44	R	3/7/89	---	--	2
26 \	M	58	R	3/10/87	1/27/88	10	--
27*/	M	59	R	1/27/88	---	--	12
28	M	49	R	9/10/84	---	--	33
29 \	M	49	L	2/17/84	---	--	60
30 /	M	53	R	2/2/88	---	--	13
31	M	58	R	11/29/84	---	--	55
32	M	48	L	8/27/84	10/24/85	14	--
33	M	49	L	8/10/84	---	--	8
34 \	F	36	L	7/20/84	---	--	58
35 /	F	38	R	1/8/86	---	--	40
36	M	63	R	8/10/87	---	--	22
37	M	55	R	12/27/85	---	--	5
38 \	F	25	R	9/13/84	---	--	58
39 /	F	26	L	9/6/85	---	--	46
40	F	61	L	5/22/85	---	--	49
41	F	50	L	11/15/84	---	--	55
42	M	51	L	10/26/84	---	--	52
43	M	59	R	5/19/85	9/17/86	16	--
44 \	F	56	L	12/4/85	3/30/88	28	--
45*/	F	59	L	3/30/88	---	--	15
46 \	M	46	R	11/13/85	---	--	40
47 /	M	46	L	11/27/85	---	--	39
48	F	55	R	7/26/85	---	--	9
49	F	63	R	10/18/85	1/ /89	38	--

CASE #	SEX	AGE	HIP	SURGERY DATE	FAIL DATE	FAIL TIME	SUCCESS TIME
50	F	52	L	1/29/86	---	--	36
51 \	F	46	R	2/5/86	3/26/86	2	--
52*]	F	46	R	3/26/86	11/14/86	8	--
53*/	F	46	R	11/14/86	---	--	31
54	F	57	R	4/2/86	---	--	35
55 \	F	26	R	3/30/88	---	--	13
56 /	F	27	L	4/5/89	---	--	1
57	M	51	R	9/23/86	---	--	10
58	M	36	L	12/23/86	---	--	10
59	M	31	L	5/28/86	---	--	32
60	M	50	R	5/15/86	---	--	37
61 \	F	38	R	7/21/86	---	--	35
62 /	F	38	L	10/20/86	5/4/89	30	--
63 \	M	65	R	11/25/86	5/30/89	30	--
64*/	M	67	R	5/30/89	---	--	1
65 \	F	49	L	12/16/86	10/13/87	10	--
66*/	F	50	L	10/13/87	---	--	3
67 \	F	74	R	1982	1983	12	--
68*/	F	75	R	1983	4/7/87	48	--
69	M	70	L	3/22/88	---	--	23
70	M	70	R	7/17/87	---	--	24
71	M	53	R	1980	---	--	96
72	F	27	L	9/29/87	6/19/89	21	--
73	F	16	R	10/20/87	---	--	20
74	F	55	R	1/3/89	---	--	4
75	M	19	L	2/16/89	---	--	3
76	M	65	L	4/26/88	---	--	6
77	M	34	L	9/6/88	---	--	4
78	M	13	L	9/28/88	---	--	6
79	M	34	R	2/28/89	---	--	2
80	M	53	L	5/24/89	---	--	1
81	M	17	L	5/31/89	---	--	1
82	M	36	R	3/28/89	---	--	2

* indicates revision of a TARA procedure surgery

\ indicates patients who have undergone multiple TARA surgeries
/

1. Age at time of surgery

2. Date revision surgery was needed as a result of significant pain or prosthesis loosening.

3. Time, in months, from surgery until revision was needed or failure was determined.

4. Time, in months, from date of TARA surgery until most recent follow-up visit. (after January 1, 1989)

CASE#	SEX	AGE[1]	HIP	SURGERY DATE	FAIL DATE[2]	LAST DATE[3]	DOCTOR[4]
1 \	F	28	R	12/28/79	4/28/84	---	FRB
2*/	F	32	R	4/28/84	---	6/20/89	FRB
3	M	59	L	11/13/85	---	7/21/87	FRB
4 \	M	64	R	3/16/84	---	4/28/89	ARL
5 /	M	68	L	2/23/88	---	4/28/89	FRB
6 \	M	57	L	10/9/79	6/14/82	---	FRB
7*/	M	60	L	6/14/82	---	9/4/86	FRB
8	F	66	R	12/10/86	---	4/27/89	FRB
9 \	F	40	L	8/19/80	---	---	COT
10 |	F	41	L	1/16/81	---	---	COT
11*/	F	41	L	1/16/81	8/ /82	---	COT
12	F	20	L	10/21/86	1/27/89	1/27/89	FRB
13	F	47	R	3/4/81	6/20/89	6/20/89	DER
14	F	80	L	4/1/81	---	6/20/89	WOI
15 \	F	62	L	12/12/80	7/13/82	---	WOI
16*/	F	64	L	7/13/82	DIED	1984	WOI
17 \	M	31	R	12/15/82	---	4/28/89	DER
18*/	M	32	R	8/29/84	---	4/28/89	DER
19	M	49	R	1/5/88	---	6/21/89	FRB
20	M	41	R	11/13/85	11/14/88	5/16/89	JCR
21	F	61	R	10/19/84	---	6/19/89	DER
22	F	38	L	1/11/85	---	11/11/85	FRB
23	F	17	L	9/22/88	---	5/5/89	FRB
24	M	55	L	7/13/84	---	6/20/89	ARL
25	M	44	R	3/7/89	---	5/4/89	FRB
26 \	M	58	R	3/10/87	1/27/88	2/2/89	FRB
27*/	M	59	R	1/27/88	---	2/2/89	FRB
28	M	49	R	9/10/84	---	6/5/87	DER
29 \	M	49	L	2/17/84	---	3/2/89	FRB
30 /	M	53	R	2/2/88	---	3/2/89	FRB
31	M	58	R	11/29/84	---	7/6/89	FRB
32	M	48	L	8/27/84	10/24/85	2/22/89	DER
33	M	49	L	8/10/84	---	4/18/85	ARL
34 \	F	36	L	7/20/84	---	5/15/89	FRB
35 /	F	38	R	1/8/86	---	5/15/89	FRB
36	M	63	R	8/10/87	---	6/20/89	FRB
37	M	55	R	12/27/85	---	5/19/86	FRB
38 \	F	25	R	9/13/84	---	7/6/89	FRB
39 /	F	26	L	9/6/85	---	7/6/89	FRB
40	F	61	L	5/22/85	---	6/19/89	FRB
41	F	50	L	11/15/84	---	6/19/89	FRB
42	M	51	L	10/26/84	---	2/16/89	FRB
43	M	59	R	5/19/85	9/17/86	---	FRB
44 \	F	56	L	12/4/85	3/30/88	---	FRB
45*/	F	59	L	3/30/88	---	6/30/89	FRB
46 \	M	46	R	11/13/85	---	3/9/89	FRB
47 /	M	46	L	11/27/85	---	3/9/89	FRB
48	F	55	R	7/26/85	---	4/28/86	FRB

CASE #	SEX	AGE	HIP	SURGERY DATE	FAIL DATE	LAST DATE	DOCTOR
49	F	63	R	10/18/85	1/ /89	6/20/89	ARL
50	F	52	L	1/29/86	---	1/23/89	FRB
51 \	F	46	R	2/5/86	3/26/86	6/22/89	JCR
52*]	F	46	R	3/26/86	11/14/86	6/22/89	JCR
53*/	F	46	R	11/14/86	---	6/22/89	COT
54	F	57	R	4/2/86	---	3/6/89	FRB
55 \	F	26	R	3/30/88	---	5/4/89	FRB
56 /	F	27	L	4/5/89	---	5/4/89	FRB
57	M	51	R	9/23/86	---	7/13/87	FRB
58	M	36	L	12/23/86	---	10/12/87	FRB
59	M	31	L	5/28/86	---	1/16/89	FRB
60	M	50	R	5/15/86	---	6/20/89	FRB
61 \	F	38	R	7/21/86	---	6/12/89	MRS
62 /	F	38	L	10/20/86	5/4/89	6/12/89	DER
63 \	M	65	R	11/25/86	5/30/89	5/30/89	FRB
64*/	M	67	R	5/30/89	---	5/30/89	FRB
65 \	F	49	L	12/16/86	10/13/87	---	FRB
66*/	F	50	L	10/13/87	---	1/14/88	FRB
67 \	F	74	R	1982	1983	---	COT
68*/	F	75	R	1983	4/7/87	---	COT
69	M	70	L	3/22/88	---	6/19/89	FRB
70	M	70	R	7/17/87	---	7/6/89	FRB
71	M	53	R	1980	---	7/21/88	COT
72	F	27	L	9/29/87	6/19/89	6/19/89	FRB
73	F	16	R	10/20/87	---	6/21/89	FRB
74	F	55	R	1/3/89	---	5/15/89	FRB
75	M	19	L	2/16/89	---	5/8/89	JKS
76	M	65	L	4/26/88	---	11/7/88	FRB
77	M	34	L	9/6/88	---	1/16/89	FRB
78	M	13	L	9/28/88	---	4/6/89	FRB
79	M	34	R	2/28/89	---	4/27/89	FRB
80	M	53	L	5/24/89	---	6/6/89	FRB
81	M	17	L	5/31/89	---	6/13/89	DAF
82	M	36	R	3/28/89	---	5/17/89	FRB

* indicates revision of a TARA procedure surgery

\ indicates patients who have undergone multiple TARA surgeries
/

1. Age at time of surgery

2. Date revision surgery was needed as a result of significant pain or prosthesis loosening.

3. Date patient was last seen in an office visit or was contacted by telephone for follow-up.

4. Name of the doctor who performed the surgery. All of the doctors were employed at Orthopaedics Indianapolis, Inc. at that time except for Dr. Townley of Port Huron, Michigan.

FRB	Dr. F. Robert Brueckmann
DAF	Dr. David A. Fisher
WOI	Dr. William O. Irvine
ARL	Dr. Anthony R. Lasich
JCR	Dr. Joseph C. Randolph
DER	Dr. Donald E. Russell
JKS	Dr. John K. Schneider
MRS	Dr. Mark R. Stevens
COT	Dr. Charles O. Townley

APPENDIX B

(Speech Text)

SLIDE 1--TITLE

SLIDE 2--JOINT ANATOMY

In September, 1940, Dr. Austin Moore inserted the first metal prosthesis into a human hip.[20,24] In the nearly fifty years since that landmark date, arthroplasty, or the replacement of bones and joints with prostheses, has developed considerably.

Conventional total hip replacement, where the entire head of the femur and the greater trochanter are removed and the center of the femur shaft reamed, has been used successfully in elderly patients with advanced hip disease. This success is due largely to the sedentary activity level of these patients and the age of these patients, since they often die before the prothesis loosens.[6] However, younger, more active patients will most likely outlive the fixation of the components and will require further revisions.[6] For this reason, a more conservative total hip replacement procedure is recommended for younger patients.[5,13]

Total Articular Replacement Arthroplasty, or the TARA procedure, invented by Dr. Charles Townley, is one type of conservative treatment and has been used since 1952.

SLIDE 3--OBJECTIVES

The major objectives of the TARA design are to preserve healthy bone stock, maintain the normal anatomy and mechanics of the hip joint, and to approximate the normal transmission of stress to the supporting femoral bone.[27]

SLIDE 4--SURGERY

The TARA procedure eliminates many of the mechanical and physiological factors that have led in the past to prosthesis failure. First, it removes the vascularly damaged portion of the femoral head.[27] This reduces the potential for further collapse of the damaged bone since the diseased portion is excised prior to seating the implant in place. Second, the mechanical design of the TARA components provide for precise positioning during surgery.[27] The thin stem extending from the center of the cup provides a protective splinting effect on the femoral neck, helping to reduce the risk of femoral neck fractures.[8,14] Third, the flat-planed anchoring surface reduces sheer forces and provides maximum mechanical stability.[27] The femoral head is remodeled to be cylindrical in shape, providing a fitted seat for the femoral prosthesis so that only the head, not the stem, bears the substantial joint stresses. Fourth, the design of the TARA femoral prosthesis does not require reaming of the femoral neck cortex, so this critical supportive bone is not lost.[27]

The purpose of the present study was to review a group of patients who had undergone Total Articular Replacement Arthroplasty using the TARA procedure. The information gathered was used to determine how long after the initial operation the components could be expected to remain intact, and to make a correlation between the age of the patient and the success of the prostheses.

MATERIALS AND METHODS

From December 1979 through May 1989, eighty-two TARA procedures were performed in 62 patients. Those patients whose surgery involved arthroplasty, revision or removal of a prosthesis, cup arthroplasty, hemiarthroplasty, or any other total hip replacement which involved the TARA procedure, were included in this study. These patients were seen in an office visit or were followed by a telephone interview after January 1, 1989. The average length of follow-up was 28.6 months. There were twenty-seven females and thirty-five males. The average age at the time of surgery was 49 years, ranging from thirteen to eighty years. Twenty-eight patients had involvement of the right hip; twenty-seven, of the left hip; and seven patients had bilateral involvement. The initial operations were performed by eight orthopaedic surgeons at Orthopaedics Indianapolis, Inc. in Indiana, and one orthopaedic surgeon in Michigan.

SLIDE 5--DIAGNOSIS

The diagnoses of the patients can be grouped into three distinct categories; degenerative joint disease, avascular necrosis, and rheumatoid arthritis. 64.5% of the patients had a diagnosis of degenerative joint disease, characterized by degeneration of the joint cartilage. This is most likely caused by advancing age and long continued use, especially in weight bearing joints. Degenerative joint disease is rarely disabling unless the hip joint is involved.[1,19] 27.4% of the patients were diagnosed with avascular necrosis. This condition results when the blood supply to the head of the femur is limited causing bone cell death, and may be caused by trauma to the joint area, high corticosteroid use, alcoholism, renal transplant complications, lupus erythematosus, and a variety of other factors.[10] 6.5% of the patients had a diagnosis of rheumatoid arthritis. This is a chronic, progressive disease, causing pain, stiffness, muscle atrophy, and eventual deformity. The cause of rheumatoid arthritis has been linked to heredity, infection, and the metabolic process, among other possibilities.[1] One (1.6%) patient's diagnosis was not recorded.

SLIDES 6-11--COMPONENTS

The implants used in the TARA procedure consist of a spherical chrome cobalt femoral cup and a polyethylene acetabular component.[27] The inner anchoring surface of the femoral implant is a flat-topped cylinder which caps the remodeled femoral head. The acetabular implants are hemispherical cups whose inner diameters match the femoral heads.

SLIDE 12--INGROWTH

To fix the implants to the bone, an acrylic bone cement is used, or porous-coated components are used to allow for biological fixation. Porous-coating consists of chrome cobalt metal beads bonded to the implant surface which increases the surface area and provides pores for the bone to grow into the metal and become fixed without the need to use any cement.[11,15]

INCIDENCE OF FAILURE

SLIDE 13--CRITERIA

In order to determine failure, the following criteria were used.

1. Removed prosthesis
2. Components revised
3. Significant pain

Specific questions about the significance of pain included: the ability to walk without a cane or crutches, the amount of pain medication being taken, the amount of range of motion available to perform daily activities, stair climbing ability, and pain or stiffness caused by sitting, standing, or walking.

SLIDE 14--RATE

Altogether, there were twenty procedure failures in eighteen patients. This gives an overall failure rate of 24.4%, implying that one in every four hip replacements involving the TARA procedure failed when performed by one of the doctors involved in this study. A vast majority of the failures occurred during the first three years following surgery.

SLIDE 15--IMPLANTS

Ten of the failures involved the acetabular component; eight, involved the femoral component; and two, involved both components. The average age of these patients was fifty years old, providing evidence that the younger, more active patients put more stress on the implants, inducing an increased chance of failure. The average length of time before these patients experienced prosthesis failure was 27.6 months, ranging from two months to one hundred months.

SLIDE 16--GENDER

It is interesting to note that more than twice as many women experienced failure as men, even though more men underwent surgery. This may be due to the smaller size of bones in females, the degenerative characteristics of female bones as they age past menopause, and the general softer bone quality found in females which is unable to stabilize the prostheses. This result is contradictory to previously reported studies.[9,22]

SLIDE 17--AGE

Also, those patients between the ages of forty and sixty years of age were twice as prone to failure as those patients older than sixty or younger than forty years of age. This may be due to the lower activity level of the older patients, a less amount of time allowed for follow-up so that the procedure had not had an opportunity to fail, or the stronger and more dense bone stock found in the younger patients.

DISCUSSION

The incidence of failure in this study is unacceptably high, though it is an improvement over previously reported results involving total hip replacement. In other studies, including both conventional and conservative hip arthroplasty, the reported failure rates have varied widely. Generally, those studies involving the TARA procedure have produced the most promising results.

To help reduce the rate of failure, loosening of the components needs to be controlled and prevented. Mechanical forces can be reduced to reach this end. Joint forces produced by the hip musculature, the patient's activity level, and the patient's body weight may lead to a breakdown in the fixation of the components. Limiting these forces, and proper positioning and cementing of the components may help to promote stability. Biologically, loosening may be influenced by the advancing degenerative disease characteristics of the bone, infection, and hormonal and steroidal factors. As the biomechanical design of the prostheses improve and the cement versus porous-coat fixation debate is resolved, lower rates of failure should result. Excellent results can be obtained if proper surgical technique is adhered to and strict selection criteria is followed.[7]

The TARA procedure has shown to be an excellent choice for total hip replacement in younger patients. It's conservative nature not only allows for further revisions, but it uses the patients' youthful structural characteristics such as strong bone stock and minimal vascular damage to a definite advantage. It's immediate results in decreasing the pain and increasing the range of motion make the TARA procedure very satisfactory to the patients, an impression reflected often in the conversations shared by those involved in this study.

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